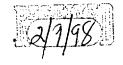




January 28, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204



Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following and statements:

European men have been supplementing their diet for many years with saw palmetto. Saw Palmetto contains nutritious phytonutrients that may play an important role in maintaining normal urinary tract functions in many men over 50.

on the following product:

Spring Valley ® Saw Palmetto

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Regulatory Affairs Associate

> LET 1380 57056